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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/446,783	05/16/00	SOON-SHIONG	P VPHAR1460-2

EXAMINER	
DEWITTY, R	
ART UNIT	**PAPER NUMBER**
1616	

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STEPHEN E REITER
GRAY CARY WARE & FREIDENRICH
4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO CA 92121

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

*U S GPO 2000-473-000/44602

Office Action Summary	Application No. 09/446,783	Applicant(s) SOON-SHIONG ET AL.	
	Examiner Robert M DeWitty	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *53-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claims 1-65 are presently pending in the instant application.

Claims 53-65 are withdrawn from the further consideration.

Election/Restrictions

1. Claims 53-65 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in an oral communication to the Examiner.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Drawings

3. The drawings filed on May 16, 2000 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. The disclosure is objected to because of the following informalities: It is noted that the application contains a blank page at page 152.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 45-46, and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Desai et al.

Desai et al. (U.S. Pat. No. 5,916,596) teaches methods for the in vivo delivery of Insoluble pharmacologically active agents in the form of suspended particles coated with protein. The method of manufacture yields particles with diameters less than 1 micron (abstract). The invention provides a drug delivery system in either liquid form or in the form of a redispersible powder (col. 1, line 36-38). In a particular embodiment, a composition of the anti-cancer drug Taxol, can be embodied in the form of nanoparticles in a liquid dispersion or as a solid which can be easily reconstituted for administration (col. 6, lines 56-59). Delivery of the active agent can occur by various methods such as

oral, intravenous, subcutaneous, intramuscular, inhalation, topical, and transdermal (col. 8, lines 17-22).

Thus, the above claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1--44, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al. further in view of Langer, C.J.

As stated above, Desai et al. teaches (U.S. Pat. No. 5,916,596) teaches methods for the in vivo delivery of insoluble pharmacologically active agents in the form of suspended particles coated with protein, such active agents including Taxol. Further, it is taught that the lethal dose of the formulations is substantially higher than current commercial formulations (such as Bovine Serum Albumin). Still yet, it is taught that this is clinically important because higher doses of chemotherapeutic drugs administered may have more effective oncolytic activity with greater reduced toxicity (col. 26, lines 15-20). However, Desai et al. does not teach dosage amounts of the formulations.

Langer, C.J. et al. ("Paclitaxel (1-hour) and carboplatin" (Abstract)) teaches infusion of paclitaxel at 135 mg/m^2 and 200mg/m^2 by 1-hour infusion. This protocol was followed every 3 weeks. Langer, C.J. et al. concludes that higher doses of formulation

yield intolerable toxicity, and the protocol was limited at paclitaxel doses exceeding 215mg/m^2. It is further taught that lower doses appear to associated with lower response rates.

Based on the art available at the time of the invention, one with ordinary skill in the art would have known to make particles comprised of an active agent such as Taxol for in vivo delivery. One with ordinary skill in the art would have been motivated to do this in order to obtain a formulation for in vivo delivery of Taxol at a higher concentration (for increased or more effective response) while at the same time limiting or reducing the toxicity of the active agent. Based on this motivation, the administration of Taxol at the concentration and administration period as taught in the instant invention would have been known to one of ordinary skill in the art.

Thus, the invention is made obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
March 10, 2001

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616